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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/853,292	05/09/97	TOVEY	23164-1003

EXAMINER: M

HM12/0413

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ART UNIT	PAPER NUMBER
FITZGERALD D	
1646	9

DATE MAILED: 04/13/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 01 Feb. 1999

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-18 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1998-404-496/40517

1. The amendments to the claims have obviated the outstanding rejections under 35 U.S.C. § 112, second paragraph (¶ 2 of the Office action mailed 28 September 1998, Paper No. 5).

Insofar as the rejections of record are maintained below, applicant's arguments filed 01 February 1999 have been fully considered, but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The objection to claims 13 and 14 as being duplicative is maintained for the reasons stated at ¶ 1 of Paper No. 5.

Applicant urges that because there may be a possibility that a type II IFN other than IFN-γ will someday be identified, the claims should be construed as differing in scope. This argument is not persuasive because the terms "type II IFN" and "IFN-γ" are merely labels which arose from the historical development of the art. However, at the time of the invention, it was recognized in the art that while "type I" IFNs (α, β, ω, and τ) comprise a plurality of subtypes, only one type II gene, IFN-γ exists. The meanings of the two terms had become entirely synonymous; nothing in the present disclosure suggests anything to the contrary. Two claims to the same genus do not differ in scope merely because they employ different words to name the genus.

3. The rejection of claims 1, 2, 4, 5, 10, and 11 under 35 U.S.C. § 102(b) as anticipated by Cummins (U.S. Patent No. 5,019,382) is maintained for the reasons set forth at ¶ 4 of Paper No. 5.

Applicant traverses this rejection on the basis that the 0.7 IU/lb. administered in the Cummins protocol is less than the 21.4 IU/kg required by the amended claims. Applicant's argument neglects to take into account, however, that the individual 0.7 IU/lb doses in the prior art are equated with the "lesser amounts" of the instant claims, not the total dosage recited in claim 1. As demonstrated in the last Office action, the total amount of IFN administered over the 21-day protocol exemplified in the reference meets the limitations of the instant claims.

4. The rejection of claims 1-8, 10-12, and 15-18 under 35 U.S.C. § 102(b) as anticipated by Samo (*J. Infect. Dis.*, 1984) is maintained for the reasons elaborated at ¶ 5 of Paper No. 5.

It is first urged that the reference does not describe oromucosal delivery of IFN. As the passage of the specification cited by applicant evidences, however, oromucosal delivery comprehends any method which effects delivery of the therapeutic agent into the oropharyngeal cavity, including in particular intranasal deliver. Applicant also argues that the description of the term "requires more than just internasal [*sic*, intranasal?] delivery." However, no example or teaching in the specification instructs any method of intranasal delivery other than that conventionally employed in the art. The cited passage thus appears to constitute no more than descriptive matter relating to the desirable features of the conventional delivery methods.

Applicant also alleges that Samo does not meet the limitations of the claims because it describes a pathological response to the administration of the IFN. The amount of IFN employed by the reference falls squarely within the amount recited in the claim. Were applicant to persist in this argument, it would raise serious questions regarding the scope of enablement *vis-à-vis* the claimed subject matter under 35 U.S.C. § 112, first paragraph. The claims should thus be construed in a manner which does not assume that the claimed dosage necessarily renders at least some of their subject matter inoperative. The limitation in question requires that the recited dosage "not induce a pathological response . . . when administered parenterally." The examiner construes this limitation to be satisfied if no pathological response is observed upon administration of the recited dosage via at least one parenteral route. Because the present specification implicitly teaches that the dosage employed by the prior art meets the limitation so construed, applicant's argument is not persuasive.

Applicant further argues that claim 2 requires "treatment" whereas the reference describes only prophylactic use. As prophylaxis to prevent or attenuate development of any given condition is recognized in the art as a method of "treatment," it reasonably appears that the method described in the prior art meets the limitations of claim 2.

5. The rejection of claims 1-3, 5, 13, and 14 under 35 U.S.C. § 102(b) as anticipated by Iida (*Vaccine*, 1989) is maintained for the reasons set forth at ¶ 4 of Paper No. 5.

Applicant traverses this rejection with only reference to the arguments advanced against the rejection over the Samo reference. For the reasons noted in the paragraphs above, these arguments are not persuasive.

6. Claim 9 remains rejected under 35 U.S.C. § 103(a) as being unpatentable over Iida (*Vaccine*, 1989) for the reasons stated at ¶ 8 of Paper No. 5.

Applicant's argument is predicated on the assumption that a *prima facie* case of obviousness necessarily requires a suggestion in the prior art of a result *better* than any prior art embodiment. That is not the law. The prior art must expressly or implicitly provide some suggestion to make the invention claimed, but a suggestion of a better result is not a prerequisite to a finding of obviousness. Applicant's attention is again invited to *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069 (CCPA, 1980), which is on-point with the elements of the instant factual and legal situation.

It remains that the instant disclosure evidences no result which would not have been expected in view of the teachings of the prior art. The proper *prima facie* case of obviousness set forth in the last Office action has not been successfully rebutted by applicant's argument.

7. The rejection of claims 1-18 under 35 U.S.C. § 103(a) as unpatentable over Cummins in view of Samo or Iida is maintained for the reasons set forth at ¶ 9 of Paper No. 5.

Applicant urges that the prior art does not suggest the use of the dosages claimed because Cummins exemplifies lower doses as preferred embodiments and because Samo notes some adverse side-effects associated with conventional doses. This line of argument was anticipated in the rationale supporting the rejection as explicated in the last Office action and is not persuasive for the reasons set forth therein. The dosages claimed are within the ranges conventionally and routinely employed in the art for the treatment of a variety of diseases, notwithstanding certain well-document adverse side effects; such side effects by themselves do not teach away from the use of the conventional dosages. Additionally, the prior art is relevant for everything it teaches or would have suggested to one having ordinary skill in the art at the time of the invention, not merely the exemplified or preferred embodiments in any one or more of the references. Applicant's arguments are therefore not persuasive.

8. The examiner believes that he has addressed all pertinent arguments. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

*A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED. ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(A) WOULD THEN BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.*

10. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

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All formal papers	(703) 308-4242
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Inquiries of a general nature should be directed to the Technology Center 1 receptionists at (703) 308-0196.

DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646

12 April 1999